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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,877	11/26/2003	Ken-Yuan Chang	CHAN3233/EM	6012

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EXAMINER	
ROBERTSON, JEFFREY	
ART UNIT	**PAPER NUMBER**
1712	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,877	CHANG ET AL.	
	Examiner	Art Unit	
	Jeffrey B. Robertson	1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *5-7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Regarding the brief description of drawings section on page 6 of the specification, the description of Figure 1 set forth therein does not appear to correlate with the Figure itself. Also, there is no brief description of Figure 8 on page 6.

Appropriate correction is required.

Claim Objections

2. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. For claim 5, the claim sets forth that R_2 is hydrogen. However, claim 1 requires that R_2 is an alkyl group and therefore, claim 5 fails to further limit claim 1.

3. Claims 6 and 7 are objected to because of the following informalities: for claims 6 and 7, these claims fail to identify the type of molecular weight, i.e. number average or weight average molecular weight, set forth in the claim. Appropriate correction is required.

Prior Art Rejections

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4-7, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Seo et al. (U.S. Patent No. 6,616,941).

For claims 1 4, and 7, Seo teaches that PLGA/PEG copolymers are prepared where R_3 is methyl and the molecular weight of the hydrophilic block is 2000. These block copolymers have the same structure as set forth in formula (I) because methoxylated polyethylene glycol is used so that diblock copolymers are formed. See Example 4. For claim 6, Seo teaches that the molecular weight of the hydrophobic portion is preferably between 1,000-10,000, significantly overlapping the range set forth by applicant. Col. 4, lines 7-10. For claims 5, 9, and 10, it is the examiner's position that the properties claimed by applicant would be inherent to the composition since the polymers claimed are the same as those disclosed in the Seo reference.

6. Claims 1, 4-7, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Seo et al. (US 2003/0017206 A1).

For claims 1 4, and 7, Seo teaches that PLGA/PEG copolymers are prepared where R_3 is methyl and the molecular weight of the hydrophilic block is 5000. These block copolymers have the same structure as set forth in formula (I) because methoxylated polyethylene glycol is used so that diblock copolymers are formed. See paragraphs [0085] and [0086]. For claim 6, Seo teaches that the molecular weight of

the hydrophobic portion is preferably between 100-100,000, significantly overlapping the range set forth by applicant. Paragraph [0050]. For claims 5, 9, and 10, it is the examiner's position that the properties claimed by applicant would be inherent to the composition since the polymers claimed are the same as those disclosed in the Seo reference.

7. Claims 1, 2, 4-7, 9, and 10 are rejected under 35 U.S.C. 102(e) as anticipated by Seo et al. (US 2005/0201972 A1).

It is noted that the examiner is relying on the filing date of the provisional application. Inspection of the provisional application revealed that the passages relied on by the examiner below are supported by the provisional application.

For claims 1 4, and 7, Seo teaches that PLGA/PEG copolymers are prepared where R_3 is methyl and the molecular weight of the hydrophilic block is 5000. These block copolymers have the same structure as set forth in formula (I) because methoxylated polyethylene glycol is used so that diblock copolymers are formed. See paragraph [0166]. For claim 6, Seo teaches that the molecular weight of the hydrophobic portion is preferably between 200-20,000, significantly overlapping the range set forth by applicant. Paragraph [0071]. For claim 2, Seo teaches that the hydroxyl terminal group is substituted by a cholesterol group. See paragraph [0072] and Example 11, paragraph [0182]. For claims 5, 9, and 10, it is the examiner's position that the properties claimed by applicant would be inherent to the composition since the polymers claimed are the same as those disclosed in the Seo reference.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art.are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 4-7, 9, and 10 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fowers et al. (U.S. Patent No. 6,592,899).

For claims 1, 4, and 7, Fowers teaches that PLGA/PEG copolymers are prepared where R_3 is methyl and the molecular weight of the hydrophilic block is 2000. See Example 9. Note the definition of PLGA in col. 5, lines 54-60. These block copolymers have the same structure as set forth in formula (I) because methoxylated polyethylene glycol is used so that diblock copolymers are formed. For claim 6, Fowers teaches that the molecular weight of the hydrophobic portion is between 400-10,000, significantly overlapping the range set forth by applicant. Col. 6, lines 5-8. For claims 5, 9, and 10, it is the examiner's position that the properties claimed by applicant would be inherent to the composition since the polymers claimed are the same as those disclosed in the Fowers reference.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (US 2005/0201972 A1) as applied to claims 1 and 2 above.

For claim 8, Seo teaches the limitations of claims 1 and 2 as set forth above. Seo fails to expressly teach the particular ranges as set forth in claim 8. The examiner's position is that these ranges are result effective variables that depend on the desired level of hydrophobicity and hydrophilicity of the resulting copolymer. A result effective variable is determined according to the desired properties of the resulting composition and would be obvious to one of ordinary skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Allowable Subject Matter

11. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. None of the references applied above, particularly the Seo et al. (US 2005/0201972 A1) reference, does not teach or suggest the group set forth in claim 3.

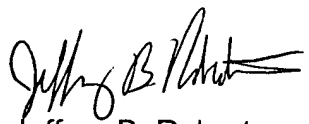
Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rathi et al. (U.S. Patent No. 6,004,573), Rathi et al. (U.S. Patent No. 6,117,949), Shah (U.S. Patent No. 6,541,033), and Seo et al. (U.S. Patent No. 6,916,788) are cited for general interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey B. Robertson whose telephone number is (571) 272-1092. The examiner can normally be reached on Mon-Fri 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey B. Robertson
Primary Examiner
Art Unit 1712

JBR